IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Krotkiewski, M	Art Unit: 1655
Appln. No.:	10/585,546	Examiner: Hoffman, Susan Coe
Filed :	March 2, 2009	Confirmation No. 5814
For :	FORMULATION FOR TREATING OBESITY AND ASSOCIATED METABOLIC SYNDROME	

APPEAL BRIEF UNDER 37 C.F.R. § 41.37(c)

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This is an Appeal Brief in support of the Notice of Appeal from the Examiner's final rejection of claims 1-3, 5-8 and 17 in the Office Action dated March 14, 2011.

Inasmuch as the instant Appeal Brief is being timely filed well within the two month period from the date of filing of the Notice of Appeal, no extension of time is necessary. However, if an extension is deemed by the Patent and Trademark Office to be necessary, the same is hereby requested, and the Patent and Trademark Office is hereby authorized to charge any fees necessary to preserve the pendency of this application to Deposit Account No. 50-2929, referencing Docket No. PZ3051573.

2. APPEAL BRIEF UNDER 37 CFR §41.37(c) (1)

The following is a Table of Contents for this Brief, with Roman numeral indicators in compliance with 37 CFR §41.37(c) (1).

Table of Contents

(i) Real Party of Interest

The real party in interest in this appeal is Scandinavian Clinical Nutrition I Sverige AB, Assignee of the entire interest in the above-identified application.

(ii) Related Appeals and Interferences

There are no other Appeals or Interferences known to Appellant which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the present Appeal.

(iii) Status of Claims

Claims 1-18 are pending in this application. Claims 4, 9-16, and 18 have been withdrawn from consideration by the Examiner and claims 1-3, 5-8 and 17 are on appeal. Appellant presents the below chart of the claims on appeal for the convenience of the Board in identifying independent claims and the claims dependent thereon.

Independent claims	Dependent claims
Claim 1	2, 3, 5- 8, 17
Claim 9	10, 11, 12, 13, 14, 15, 16

(iv) Status of Amendments

The Amendment after the final rejection filed by Appellant has been entered by the Examiner. (See Advisory Action mailed on June 29, 2011)

(v) Summary of Claimed Subject Matter

The claimed invention relates to a formulation for treating obesity and associated metabolic syndrome. (Spec., p. 1, l. 3-4)

Weight reducing programs based on calorie restriction and the rapid weight regain are considered to be caused by the decrease of metabolic rate and thermogenesis. The decrease in metabolic rate and thermogenes depends on the adaptation of the body to the changed energy balance and decreased food intake. Adaptation to low calorie intake includes, inter alia, decreased activity of the sympathetic nervous system and changes in the metabolism of thyroid hormones and towards production of the less active forms of the hormones. Decreased activity of adrenergic nervous system and changed concentration of the active form of thyroid hormones lead to decreased mobilization and oxidation of fatty acids and the decreased activity/expression of uncoupling proteins. The decrease of metabolic rate is one of the main reasons to the low rate of success of obesity treatment with more than 90% of the slimming patients returning to the start weight. (Spec., p. 1, l. 16 - p. 2, l. 2)

Calories stored in the body, mainly in a form of fat, can be burned quicker by the administration of various thermogenetic drugs resulting in a loss of body weight. However, such therapies often have negative side effects and after discontinuation of the therapy the patient's body weight goes back to the starting values before treatment. (Spec., p. 2, l. 4-8)

One of the agents recently used is Green tea extract (Green tea, *Camellia sinensis*). Green tea extract comprises large amounts of catechin polyphenols, mainly epigallocatechin gallate – EGCG. EGCG is a very strong antioxidant which reduces the appetite and leads to decreases of food intake (see Am. J. Clin. Nutr 2000, 72, pages 1232-1234). Green tea extract has been described to inhibit carbohydrate and lipid digestion and exhibits strong anti-

inflammatory activity. The thermogenetic effect of Green tea has been described in Am. J. Clin. Nutr. 1999, 70, pages 1040-1045. (Spec., p. 2, l. 10-18)

Another popular therapeutic plant is a herb growing in South America called Yerba Maté (Paraguay, *Ilex paraguariensis*). This material contains tripterpenes, caffeine and caffeine-like compounds. (Spec., p. 2, l. 19-21)

Weight-reduction activity is also exhibited by the plant-Guarana (*Paulinia cupana, P. sorbolis*) which contains large amounts of caffeine and other polyphenoles and chlorogenic acids (CGA). According to Hurel, J.P. 1993 (FR. 2,712,191 A1), caffeine included in Guarana extracts is the primary agent responsible for body weight decrease. However, use of Yerba Maté of Guarana as a single agent will result only in a momentary effect and after finishing the treatment immediate increase of body weight is observed. (Spec., p. 3, l. 3-8)

US Patent No. 5,804,596 discloses the active obtained from *Coleu Forskohlii* root extract (ForLean®). This extract contains active agent – forskolin (diterpene forskolin). The biological mechanism of diterpene forskolin activity is described in medical literature and many clinical evaluations have been performed. Those evaluations relate to different activities of diterpene forskolin e.g. broncholytic (for treating bronchial asthma), relaxation of the arteries (for treating hypertension and cardiovascular system disorders), treating glaucoma and impotence. Studies conducted on weight reduction in rats showed, that low doses of diterpene forskolin are not effective. Only use of very high doses resulted in distinct body weight reduction. However, in case of humans such high doses cause hypotensive effects and harmful high inotropic activity on heart muscle. (Spec., p. 3, l. 9-18)

The pharmacological activity of birch leaves (*Betula Alba, betulae folium, Batula pendula Roth*) was not a subject of such extensive study as in case of herbs described above but

it was widely used in Europe for quite some time. Aqueous extract of birch leaves is known as a mild diuretic agent and is used to irrigate the urinary tract, to remove sand and to prevent inflammation of urinary tract. It was also used orally. (Spec., p. 3, l. 19-25)

Human obesity can be also treated with Orlistat® which is sold under the trademark Xenical® (US Patent No. 4,598,089). Inhibition of lipase activity evoked by Orlistat means that 30% of consumed fat goes through the digestive tract without decomposition and is not absorbed. However, Orlistat exhibits some side effects such as: fatigue, headaches, stomachaches, oily diarrheas, gases and flatulence. It is not suitable for children and should not be used by pregnant and breast-feeding women. (Spec., p. 4, l. 1-8)

The object of the presently claimed invention is to provide a composition for treating human obesity, which is effective in accelerating weight loss and which would be characterized by the lack of major side effects and would help to maintain the lower body weight, obtained during slimming. The components are acting in concert (unexpectedly) strengthening together the two main effects of the mixture i.e. termogentetic effects (increased metabolic rate) and the decrease of the absorption of fat. (Spec., p. 4, l. 9-17)

Claim 1 of this invention recites a formulation containing: a) 20-90% wt. of Green tea extract, containing more than 70% of catechines, preferable containing EGCG; b) 2-30% wt. of Coleus forskohlii extract, containing at least 10% of diterpene forskolin; c) 5-58% by wt. of Yerba Maté extract, containing 2-4% by wt. of caffeine and caffeoylquinic acids (CGA), and d) 7.5-45 % by wt. of Betula alba extract containing at most 3% by wt. of flavonoids.

Guarana extract is used in the formulation of appealed claim 9, instead of Yerba Maté extract. The claim 9 formulations has the following composition: a) 20-80% wt. of Green tea extract, containing more than 70 % of catechines; b)2-30 % wt. of Coleus forskohlii extract,

containing at least 10 % of diterpene forskolin; c) 5-50% wt. of Guarana extract, containing more than 8 % of caffeine and caffeine-like polyphenoles (chlorogenic acids - CGA) , and d) 7.5-45 % wt. of Betula alba extract containing at most 3% of flavonides.

The formulation of the present invention may further comprise an effective amount of vegetable extract of white kidney beans (*Phaseolus Vulgaris*). (See claims 2 and 10)

The Green tea extract can comprise at least 30% of EGCG (claim 5 and 13) or can comprise at least 50% of EGCG (claims 6 and 14) or can comprise at least 80% of EGCG (claims 7 and 15).

Human obesity can be treated by reducing fat digestion and fat absorption. Fats must be decomposed by lipase before they are absorbed by the organism. Inhibiting lipase activity causes considerable reduction of the fat absorption which decrease calorie intake. This mechanism illustrates the activity of Roche's anti-obesity formulation Xenical® (Orlistat®).

Fig. 1 (attached as Ex. 1) shows the comparison between in vitro effect of the formulation according to the claimed invention on the activity of pancreatic lipase and various concentrations of Xenical® (0.5-100 mg) after 30, 45 and 60 minutes in temperature of 37°C. The composition of the formulation of the invention which is within the range of the claims on appeal is shown below in the Table 1:

Table 1

Component	% (wt.)
Green tea extract	82.3
Coleus forskohlii extract	2.5
Yerba Maté extract	7.6
Betula alba extract	7.6

In the case of the formulation of the claimed invention as claimed, the lipase activity was reduced after 30 minutes. Increase of time period to 45 and 60 minutes resulted in larger

reduction of lipase activity in case of lower concentrations (down to 30 mg) of the formulation of the invention. Maximum reduction of lipase activity obtained was equal to approximately 80%. Although, Xenical® (Orlistat®) inhibits the lipase activity stronger than the formulation of the invention and at concentration of 10 mg after 45 and 60 minutes cause complete inhibition of lipase activity, it leads also to negative side effects.

Example 4 of the present application shows the effect of a formulation of the claimed invention and its components on the reduction of body weight increase in rats.

Healthy rats selected to the experiment were divided into 6 groups, each receiving one of following substances: formulation of the claimed invention, *Coleus forskohlii, Betula Alba*, Yerba maté, Green Tea Extract (EGCG) and Guarana. These substances were administered orally (by gavage) in the form of solutions. During the experiment the animals were fed with Ssniff® R (purchased from Spezialdiäten GmbH, Germany) and municipal water.

12 weeks of observation of Wistar rats proved that the increase of body weight is lowest in the group treated with the formulation of the claimed invention. Values of the mean body weight increase in tested groups are presented in the Table 3 below and Fig. 2B (Attached as Ex. 2).

Table 3

Group treated with	Mean body weight increase
Formulation of the invention	59.8
Colleus forskohlii	78.2
Betula Alba	76.7
Yerba Maté	71.0
EGCG	73.9
Guarana	68.7

The increase (%) of body weight in rats during this experiment is presented in Fig. 2A (Attached as Ex. 3)

The mean amount of pellet – chow eaten by rats in appropriate group was measured. The results are presented in the Fig. 3 (Attached as Ex. 4). It is clear that the food intake is the lowest in the group treated with the formulation of the claimed invention.

The experiment proved that combination of the natural substances present in the formulation of the claimed invention is effective in reducing the body weight in rate, and acts stronger than the separate ingredients of the formulation.

Example 5 of the present application shows the effect of the formulation of the claimed invention in a study conducted on humans.

Advantageous properties of the formulation of the invention were confirmed by a study conducted on healthy volunteers. The aim of the study was to check the safety and efficacy of the invention and to examine the influence of the formulation of the claimed invention used as a food supplement on resting metabolic rate. Mean resting metabolic rate increased in the treated group from 4.3 ± 0.2 to 4.8 ± 0.2 kJ/min after 3 days (Fig. 4, attached as Ex. 5) whereas exercise metabolic rate remained unchanged (not shown).

Another human study-double blind, placebo controlled clinical study was preformed to examine the decrease of body weight of patients on low calorie diet (1000 kcal/day), body fat weight, increase of non-fat body weight (figure improvement), decrease of plasma LDL cholesterol, total cholesterol and plasma triglycerides concentration. The study lasted 14 weeks. The composition of the formulation of the claimed invention is presented below in the Table 4:

Table 4

Component	% (wt.)
Green tea extract	79.5
Coleus forskohlii extract	2.4
Yerba Maté extract	6.2
Betula alba extract	11.9

The influence of formulation of the claimed invention was examined during tests performed on 48 obese patients divided into two groups who completed the study. Both groups were received low calorie diet (1000 kcal/day), but diet of only one group was supplemented with the formulation of the invention ("treated group").

After 14 weeks, body weight decrease was equal 6.06% in the control group and9.28% in the treated group which was receiving the formulation of the invention (Fig. 5, attached as Ex. 6). Those values expressed n kilograms are equal to 5.54 kg and 8.51 kg respectively. The difference between these two groups was 53.6%. The differences were found to be statistically significant.

Decrease of body fat concentration was equal to -4.0 kg in the control group and -6.6 kg in the treated group (Fig. 6, attached as Ex. 7). Simultaneously, decrease of LDL plasma cholesterol concentration of 1.58 mg/dl in the control group and by 6.08 mg/dl in the treated group (Fig. 7, attached as Ex. 8) and total plasma cholesterol by 3.92 mg/dl and 19.42 mg/dl /(Fig. 8, attached as Ex. 9) respectively was observed. Reduction of cholesterol concentration was accompanied by decrease of plasma triglyceride concentration by 6.63 mg/dl in the treated group, while in the control group triglyceride concentration increased by 1.42 mg/dl (Fig. 9, attached as Ex. 10).

Studies have verified that the formulation as claimed accelerated weight loss during dietary treatment of obesity; and the effect of their mixture of components as claims is significantly greater than the effect of any separate component alone.

(vi) Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on Appeal are as follows:

(a) Rejection under 35 USC §112, second paragraph of claims 1-3, 5-8 and 17 as allegedly being indefinite;

(b) Rejection under 35 USC §103(a) of claims 1, 3, 5-8 and 17 as allegedly being unpatentable over U.S. Patent No. 6,610,749 to Liao, U.S. Patent No. 5,804,596 to Majeed, U.S. Patent No. 7,279,184 to Gow, U.S. Patent No. 6,251,888 to de la Harpe and BE 1009545; and

(c) Rejection under 35 USC §103(a) of claim 2 as allegedly being unpatentable over U.S. Patent No. 6,610,749 to Liao, U.S. Patent No. 5,804,596 to Majeed, U.S. Patent No. 7,279,184 to Gow, U.S. Patent No. 6,251,888 to de la Harpe and BE 1009545 further in view of US 2003/0059403 to Chokshi.

(vii) Arguments for Patentability

Appellant urges that the Examiner's rejections are not valid and Appellant urges reconsideration and withdrawal of the §112 and §103(a) rejections for the following reasons.

The §112 Rejection

The Examiner has rejected claims 1-3, 5-8 and 17 under 35 USC §112, second paragraph as allegedly being indefinite.

The Examiner alleges that the recitation of "…low metabolic rate" is indefinite. Appellant respectfully traverse this rejection and request reconsideration of this rejection.

Appellant respectfully submits that the artisan skilled in the art area of the present invention having the benefit of the present claims and supporting disclosure would be fully apprised of the scope and content of this claim term. Those skilled in the art of obesity treatment would readily recognize that control of a subject's metabolic rate has an influence on weight gain or loss and that a low metabolic rate in a subject may be a factor in leading to weight gain by the subject. The present claims which are directed to the treatment of obesity would be read by an artisan of skill in the art in light of the supporting disclosure. Such an artisan having the benefit of the present claims and the supporting disclosure would be fully apprised of the scope and content of the present claims and would know the scope and intent of the claim term "low metabolic rate".

For the above reasons, Appellant urges that this rejection is in error and appellant respectfully request reconsideration and withdrawal of the rejection or in the alternative reversal of this rejection by the Board.

The §103(a) Rejections

The Examiner has concluded that one of ordinary skill in the art would be able to arrive

at the claimed invention from a combination of the cited references.

Appellant urges that, even though the references individually mention respective ones of the constituents of the combination of constituents of the presently claimed formulation, each individual reference mentions only a single constituent of the invention, not any combination of as few as even two of the constituents.

There is no teaching or suggestion in the cited reference that would have led the ordinary artisan to combine the references with reasonably expectancy with achieving an unexpectedly better result for decreasing obesity without unwanted side effects. In that regard, it should be noted that although the Majeed reference mentions a forskolin extract, it does not disclose a coleus forskohlii extract containing at least 10 % by weight of diterpene forskolin, as is recited in the claims on appeal. The Majeed reference would allow lesser amounts to be used contrary to what is claimed herein. None of the other references relied upon by the Examiner discloses or suggests either the inclusion of that constituent or its amount in any particular combination of constituents. The ordinary artisan would have before him or her not only the reference cited by the Examiner in hindsight but many others. From this large selection of art, the artisan without the benefit of hindsight would need to choose the specific components of the claimed formulations with the expectation that the combination would provide an enhanced effect on fighting obesity.

With regard to the combination of the separately-disclosed constituents, the Examiner concluded that, "No patentable invention resides in combining old ingredients of known properties where the results obtained are no more than the additive effect of the ingredients."

However, as shown in the present application in Figs. 2A and 2B, the individual constituents green tea extract, coleus forskohlii, Yerba Matê, and Betula Alba each individually

provides substantially the same effect as the other individual constituents on body weight increase and on the mean rate of change of body weight of tested rats. In Fig. 2A there is shown that the increase in body weights of the tested rats that were fed only individual constituents of the claimed invention, and at the end of 12 weeks the effect of each individual constituent was within the narrow range of from about 42% to about 46%, whereas the corresponding increase for the claimed composition was significantly lower at about 32%. These data for the individual constituents would not lead one to combine any of them because one of ordinary skill in the art would conclude that no different effect would be produced by any such combination.

Similarly, Fig. 2B shows the mean change in body weights of the tested rats fed only individual constituents of the claimed invention. At the end of 3 months each change was within the narrow range of from about 71% to about 79%, whereas the change over that same time interval for the claimed composition was significantly lower at 60%. These data for the individual constituents would not lead one to combine any of them because one of ordinary skill in the art would conclude that no different effect would be produced by any such combination.

It is noteworthy that none of the references contains any information that would suggest any unexpected effect from any combination of the constituents as claimed. Indeed, none of the references even remotely suggests any combination of the claimed constituents. The present application provides ample evidence of an unexpected effect of the claimed invention by virtue of the examples and the tables that are included in the specification, along with Figs. 2A and 2B of the drawings.

It was acknowledged by the Examiner, that, "The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art

would routinely optimize."

However, as stated in MPEP § 2143.01, Ill., "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." (Emphasis in original) (citing the KSR case). There is no basis for concluding predictability where a composition includes five different constituents, each present in the composition in specific and varying amounts. It is suggested that the optimization conclusion could more plausibly be advanced were there only two constituents in the combination.

The presence of five different constituents, each of which is mentioned in a different reference, would require a virtually limitless number of optimization trials involving many different variations of the amounts of each of the individual constituents, while maintaining the amounts of other constituents constant, and that would each then be subjected to animal testing to ascertain their effectiveness in achieving the expected synergistic result. Clearly, such a testing program would be a hopelessly complex task, one that would be impractical from both a financial and a time standpoint, and would therefore not even be attempted by one of ordinary skill in the art.

As also stated in the MPEP, at § 2141.02 I., "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." (Emphasis in original). Considering the invention as a whole as it is claimed in the claims on appeal, the claimed invention would not have been obvious to one of ordinary skill in the art having before him/her the references that were relied upon by the Examiner.

Claims 2, 3, 5-8, and 17 each depend from claim 1, either directly or indirectly, and

therefore those dependent claims are also not obvious based upon the combinations of references that were relied upon by the examiner. Additionally, the dependent claims contain further recitations with respect to, inter alia, the amounts of individual substitutes in the formulations, that distinguish the claimed invention from the references cited by the Examiner.

It should also be noted that the present claims invention have been patented in Europe. A copy of the English-language version of the claims that were granted in Europe (EP 1 708 726 B1, granted October 15, 2008) is of record in the present application. The EPO has concluded that the present claims have satisfied each of the novelty, inventive step, and industrial applicability criteria of the European Patent Convention.

The Examiner has argued that:

"…applicant has not supported the assertion that these results are synergistic rather than additive (see MPEP section 716.02 (a)). An artisan of ordinary skill would clearly expect a combination of five weight loss ingredients to function in an increased manner in comparison with one weight loss ingredient. Thus, the showing that the combination of the five ingredients functions better than the single ingredient is not considered to be unexpected. In addition, the results shown in Figures 2A and 2B are not considered to be commensurate in scope with the claimed invention. This is because the results are only shown for one formulation that falls within the claimed percentages while the claims encompass numerous other embodiments that are not used to produce the experimental data (see MPEP section 716.02 (d))."

Appellant urges that the Examiner has either not fully understood the evidence of record or has misinterpreted the data presented in the present specification as explained above.

It has been acknowledged by the Examiner, that the references do not specifically teach adding the ingredients in the amounts recited in the present claims. There is no teaching that a

combination of the various components of the presently claimed composition could be made with the expectation that the end result would be a composition which functions in an unexpected manner and hence provides an unexpected result.

As noted above the MPEP § 2143.01 states, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." (Emphasis in original) (citing the KSR case). Appellant urges that the skilled artisan viewing the data provided in the instant specification would have concluded that the unique combination disclosed and claimed in the present application was an unexpected achievement. The Board should note that the EPO has granted a patent to Appellant based on the holding by the WIPO Examiner that the present application demonstrated an unexpected combination.

Appellant urges the Board to consider Figs. 2A and 2B, of the present application which show that the individual constituents green tea extract, *coleus forskohlii,* Yerba Mate, and *Betula Alba* each individually provide substantially the same effect as the other individual constituents on body weight increase and on the mean rate of change of body weight of tested rats. In Fig. 2A there is shown that the increase in body weights of the tested rats that were fed only individual constituents of the claimed invention, and at the end of 12 weeks the effect of each individual constituent was within the narrow range of from about 42% to about 46%, whereas the corresponding increase for the claimed composition was significantly lower at about 32%. One of only ordinary skill in the art would conclude that a combination of the individual components would provide a result which would be about the same as the individual component results, i.e., a range of between 42 to about 46% rather than an almost 30% enhanced result for the combination of the present invention.

Fig. 2B shows the mean change in body weights of the tested rats fed only individual constituents of the claimed invention, and at the end of 3 months each change was within the narrow range of from about 71% to about 79%, whereas the change over that same time interval for the claimed composition was significantly lower at 60%. Again, the artisan would not have expected a much better result for the combination whereas the combination actually gave an about 30% enhanced effect.

Appellant urges that present application provides ample evidence of an unexpected effect of the claimed invention, i.e., an about 30% enhanced result, by virtue of the examples and the tables that are included in the specification along with Figs. 2A and 2B of the drawings.

Appellant further urges that Appellant has provided further data to demonstrate the unobviousness of the presently claimed combination. Figure 1 shows a comparison of the present combination against Xenical with respect to lipase activity. Xenical is a known treatment for obesity which acts via lipase inhibition. The present combination provides significant inhibition without the negative side effects of Xenical. It would have been clear to the artisan from Fig. 3 that the mean food intake in the tested rats is lowest in the group treated with the formulation of the invention and that this effect is sufficiently significant to conclude that synergism was achieved by the invention formulation.

The Examiner also contends that the unexpected result shown by Appellant is not commensurate with the scope of the claims. Appellant urges that the Examiner has not provided any basis for this allegation. As can be seen from the results of Figs. 2A and 2B the individual components provided an approximately equivalent result with respect to the tests in these studies. The artisan would have expected similar results for all of the possible ranges of the individual components. Similarly, the artisan knowing that the combination provided an enhanced and

unexpected effect for the concentrations shown in the tests of figs. 2A and 2B would have expected similar enhanced and unexpected effects throughout the entire range recited in the instant claims. Appellant also points out that the Examiner has simply concluded that the data provided by Appellant does not demonstrate an unexpected result. No evidentiary basis is given by the Examiner that substantiates this position. Appellant urges that sufficient data and reasoning has been presented to allow a conclusion that the present combination formulation provides an unexpected result.

Appellant respectfully submits that all of the Examiner's rejections are in error and Appellant requests withdrawal of these rejections and issuance of a Notice of Allowability. If the Examiner decides to maintain any or all of these rejections, the Board is respectfully requested to reverse the Examiner's rejections.

Conclusion

Appellant submits that the prior art relied upon by the Examiner does not provide sufficient evidentiary support for an obviousness rejection of the claims on appeal.

Appellant respectfully requests a reversal of the Examiner's final rejection of all of the claims on appeal, and issuance of a Notice of Allowability by the Examiner.

Please direct any questions to the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: September 12, 2011

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(viii) Appendix of Claims

1. (Previously Presented) A formulation of plant matter extracts for treating obesity and low metabolic rate, said formulation comprising:

a) 20-90% by wt. of Green tea extract, containing more than 70 % by wt. of catechins,

b) 2-30 % by wt. of *Coleus forskohlii* extract, containing at least 10 % by wt. of diterpene forskolin,

c) 5-58% by wt. of Yerba Maté extract, containing 2-4% by wt. of caffeine and caffeoylquinic acids (CGA), and

d) 7.5-45 % by wt. of *Betula alba* extract containing at most 3% by wt. of flavonoids.

2. (Previously Presented) The formulation according to claim 1, further comprising an effective amount of extract of white kidney beans (*Phaseolus Vulgaris*).

3. (Previously Presented) The formulation according to claim 1, wherein the Green tea extract is an extract obtained under reduced pressure by at least one of water-based extraction and extraction based upon ethyl acetate and water.

4. (Withdrawn/Previously Presented) The formulation according to claim 1, wherein the Green tea extract is an extract obtained by at least one of alcohol extraction and extraction conducted in the presence of fat solvents selected from the group consisting of: methanol-chloroform mixture, alcohol ethers and detergents, at low temperature and under reduced pressure.

5. (Previously Presented) The formulation according to claim 3, wherein the Green tea extract includes at least 30% by wt. of epigallocatechin gallate (EGCG).

6. (Previously Presented) The formulation according to claim 3, wherein the Green tea extract includes at least 50% by wt. of epigallocatechin gallate (EGCG).

7. (Previously Presented) The formulation according to claim 3, wherein the Green tea extract includes at least 80 % by wt. of epigallocatechin gallate (EGCG).

8. (Previously Presented) The formulation according to claim 1, further comprising at least one of a non-active excipient selected from the group consisting of: silicon dioxide, magnesium stearate, and lauryl sulphate; a surfactant selected from the group consisting of: sodium carboxymethylcellulose. hydroxypropylmethyl cellulose, and microcrystalline cellulose; and an anti-caking agent; and combinations and mixtures thereof.

9. (Withdrawn/Previously Presented) A formulation of vegetable extracts for treating obesity and associated metabolic syndrome, said formulation comprising:

a) 20-80% wt. of Green tea extract, containing more than 70 % of catechins,

b) 2-30 % wt. of *Coleus forskholii* extract, containing at least 10 % of diterpene forskolin,

c) 5-50% wt. of Guarana extract, containing more than 8 % of caffeine and caffeine-like polyphenoles (chlorogenic acids - CGA)-, and

d) 7.5-45 % wt. of *Betula alba* extract containing at most 3% of flavonides.

10. (Withdrawn/Previously Presented) The formulation according to claim 9, including an effective amount of vegetable extract of white kidney beans (*Phaseolus Vulgaris*).

11. (Withdrawn/Previously Presented) The formulation according to claim 9, wherein the Green tea extract is an extract obtained by at least one of water and ethyl acetate and water extraction at low temperature and under reduced pressure.

12. (Withdrawn/ Previously Presented) The formulation according to claim 9, wherein the Green tea extract is an extract obtained by at least one of alcohol extraction and extraction conducted in the presence of fat solvents selected from the group consisting of: methanol-chloroform mixture, alcohol ethers and detergents, at low temperature and under reduced pressure.

13. (Withdrawn/Previously Presented) The formulation according to claim 11, wherein the Green tea extract includes at least 30% of epigallocatechin galate (EGCG).

14. (Withdrawn/Previously Presented) The formulation according to claim 11, wherein the Green tea extract includes at least 50% of epigallocatechin galate (EGCG).

15. (Withdrawn/Previously Presented) The formulation according to claim 11, wherein the Green tea extract includes at least 80 % of epigallocatechin galate (EGCG).

16. (Withdrawn/Previously Presented) The formulation according to claim 9, including non-active excipients selected from the group consisting of: silicon dioxide, magnesium stearate, and laurylsulphate; surfactants selected from the group consisting of: sodium carboxymethylcellulose, hydroxypropylmethyl cellulose, and microcrystalline cellulose; and anti-caking agents.

17. (Previously Presented) The formulation according to claim 1, wherein the catechins include epigallocatechin gallate.

18. (Withdrawn/Previously Presented) [[A]] The formulation according to claim 9, wherein the catechins include epigallocatechin galate.

(ix) RELATED PROCEEDINGS

There are no proceedings related to this Appeal.

Exhibit 1

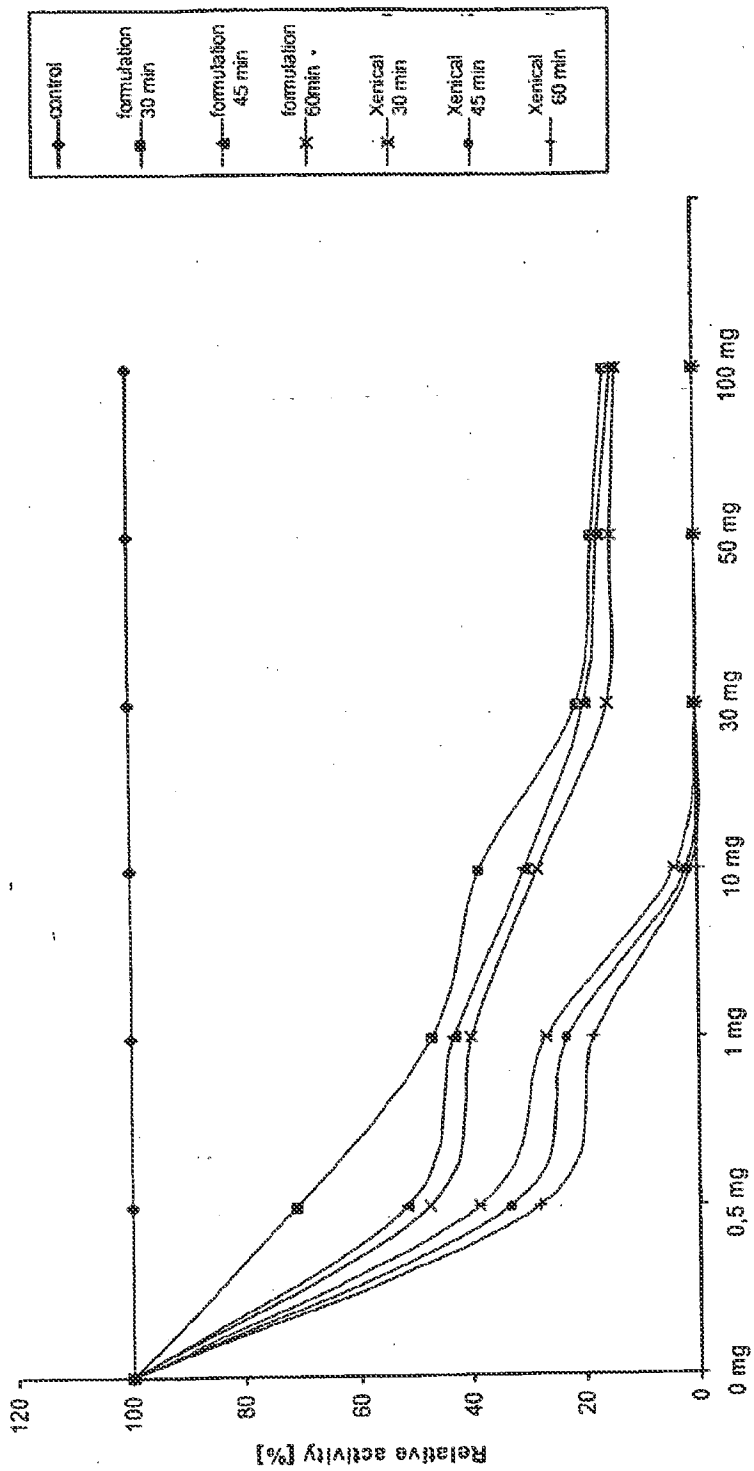
Lipase inhibitory effect of the formulation of the invention versus Xenical
Formulation of the invention containing 335 mg of Green tea extract / capsule
Relative activity [%]
120
100
80
60
40
20
0
0 mg
0,5 mg
1 mg
10 mg
30 mg
50 mg
100 mg
control
formulation 30 min
formulation 45 min
formulation 60min
Xenical 30 min
Xenical 45 min
Xenical 60 min

FIG.1

Exhibit 2

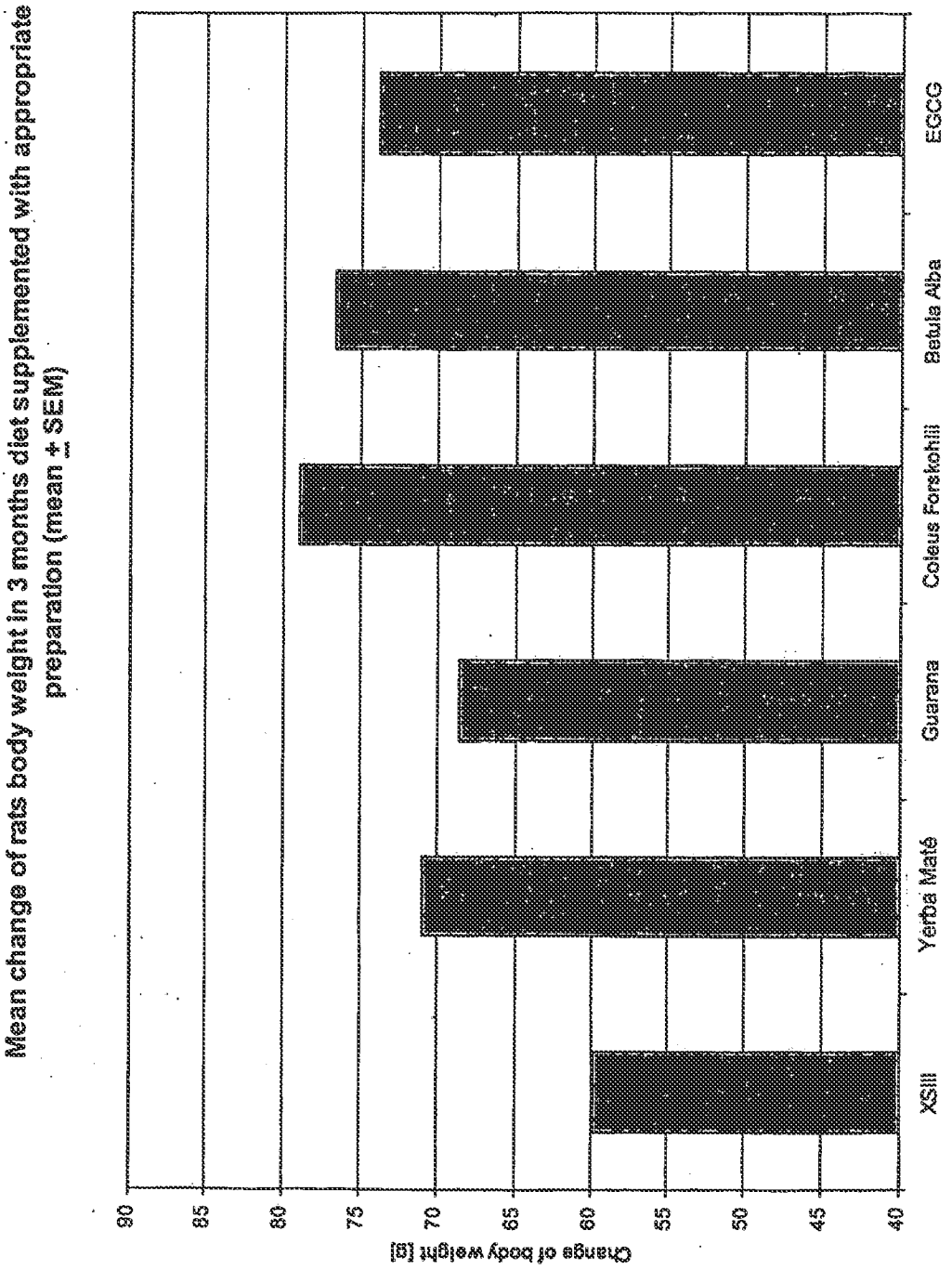
Mean change of rats body weight in 3 months diet supplemented with appropriate preparation (mean ± SEM)
Change of body weight [g]
90
85
80
75
70
65
60
55
50
45
40
XSIII
Yerba Maté
Guarana
Coleus Forskohlii
Betula Alba
EGCG

FIG. 2B

Exhibit 3

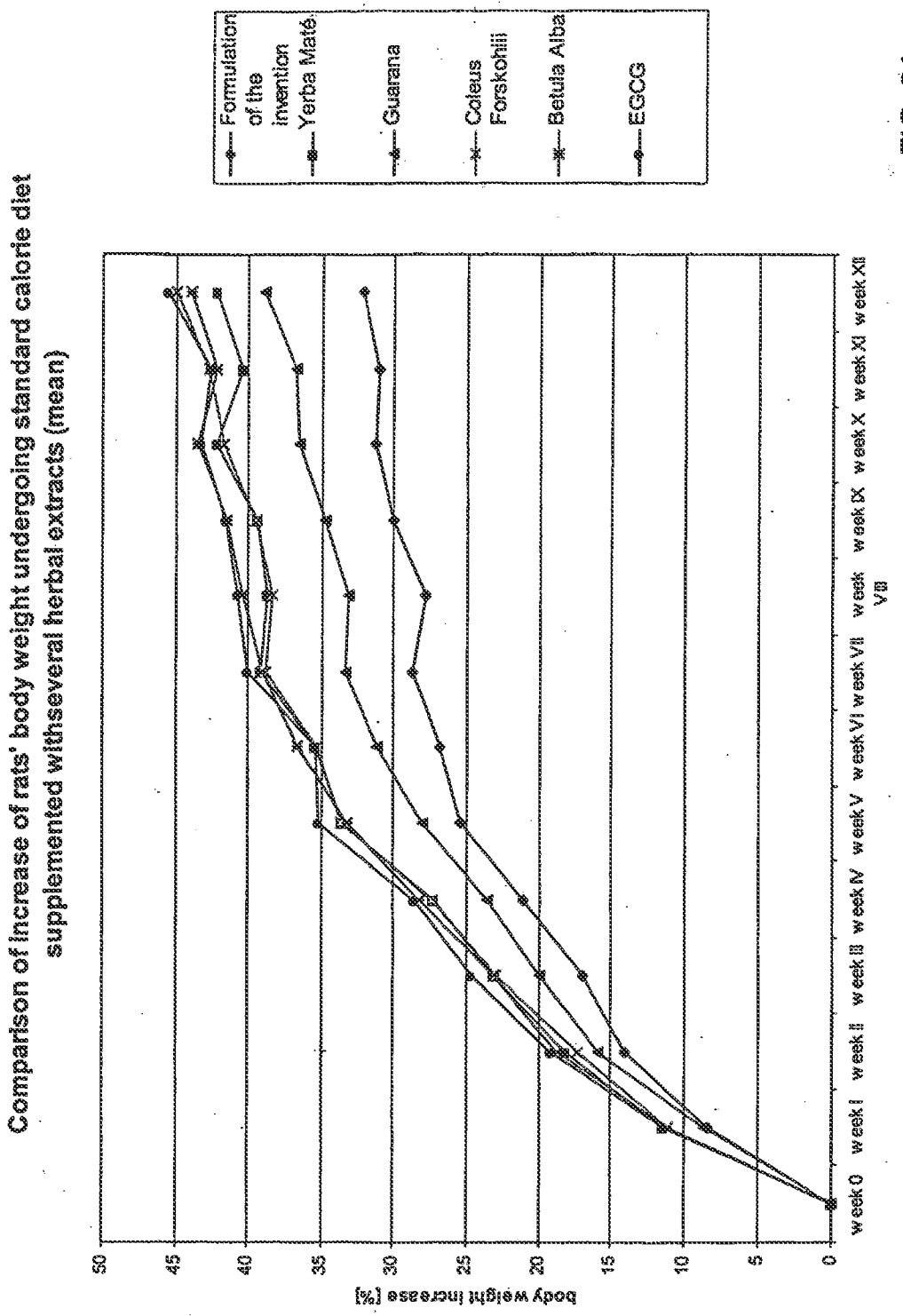
Comparison of increase of rats' body weight undergoing standard calorie diet supplemented withseveral herbal extracts (mean)
Formulation of the invention
Yerba Maté
Guarana
Coleus Forskohlii
Betula Alba
EGCG
body weight increase [%]
0
5
10
15
20
25
30
35
40
45
50
week 0
week I
week II
week III
week IV
week V
week VI
week VII
week VIII
week IX
week X
week XI
week XII

FIG. 2A

Exhibit 4

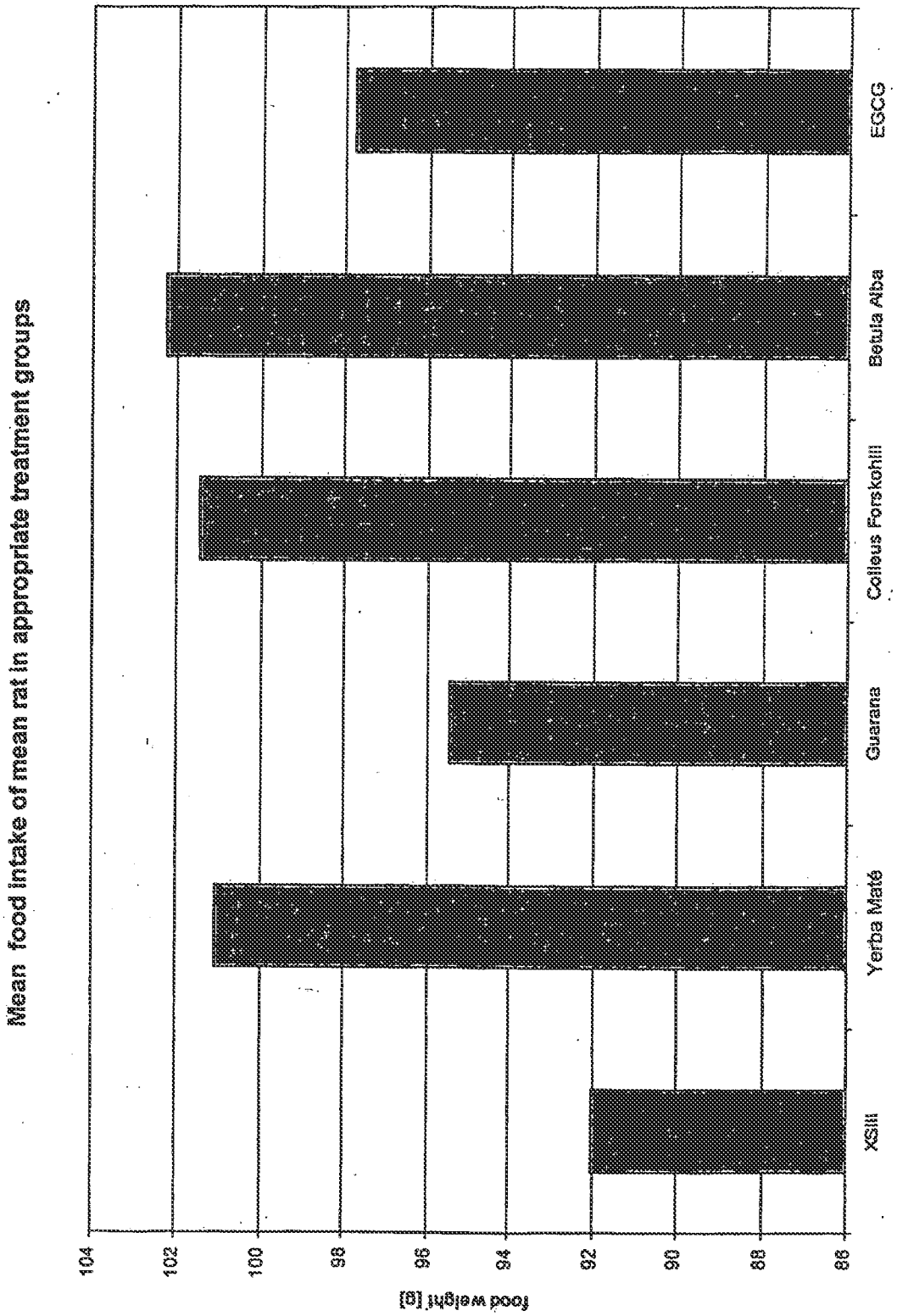
Mean food intake of mean rat in appropriate treatment groups
food weight [g]
104
102
100
98
96
94
92
90
88
86
XSIII
Yerba Maté
Guarana
Coleus Forskohlii
Betula Alba
EGCG

FIG. 3

Exhibit 5

Effectof the formulation of the invention on resting metabolic rate. Mean values.

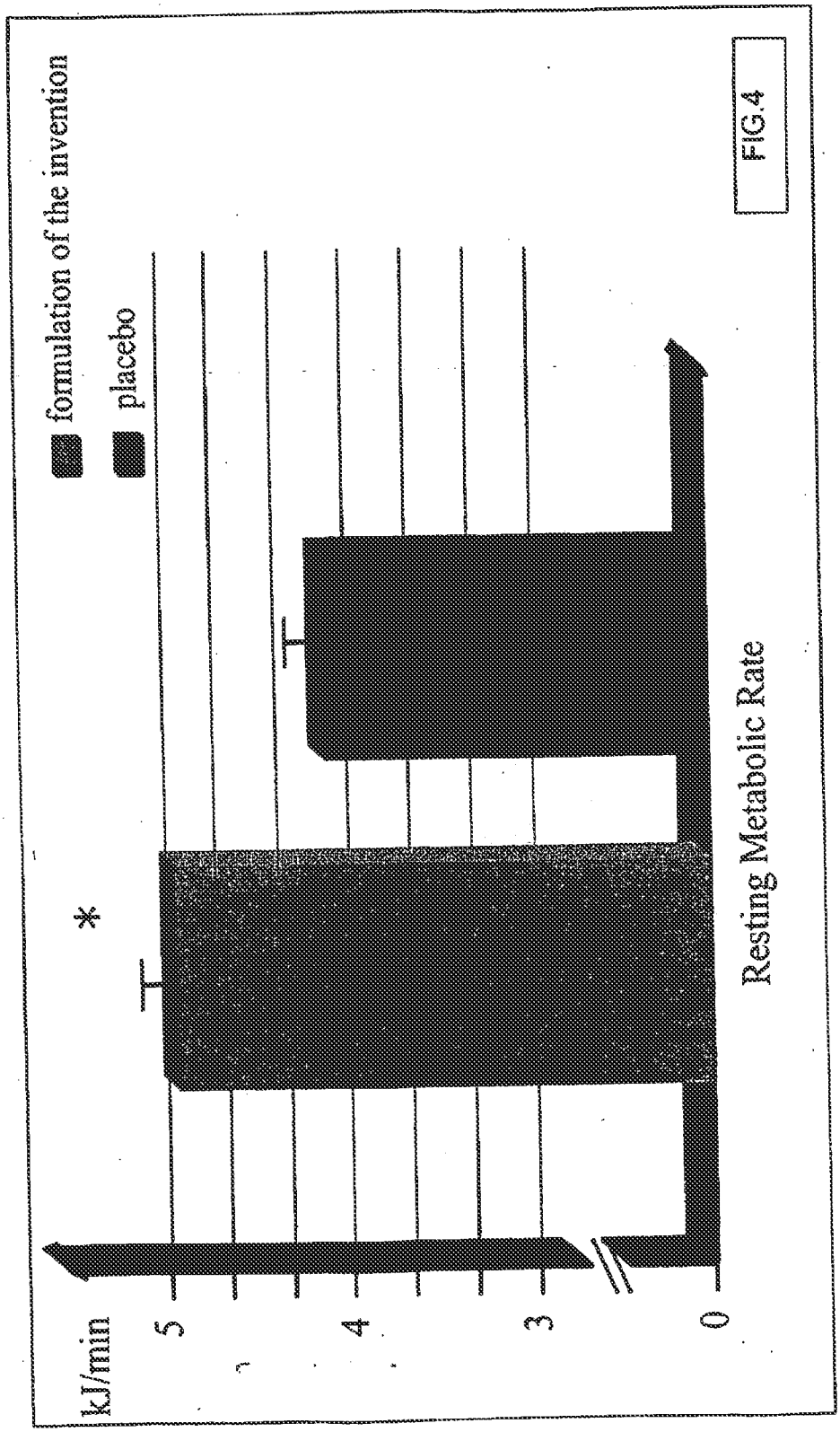

FIG.4

Exhibit 6

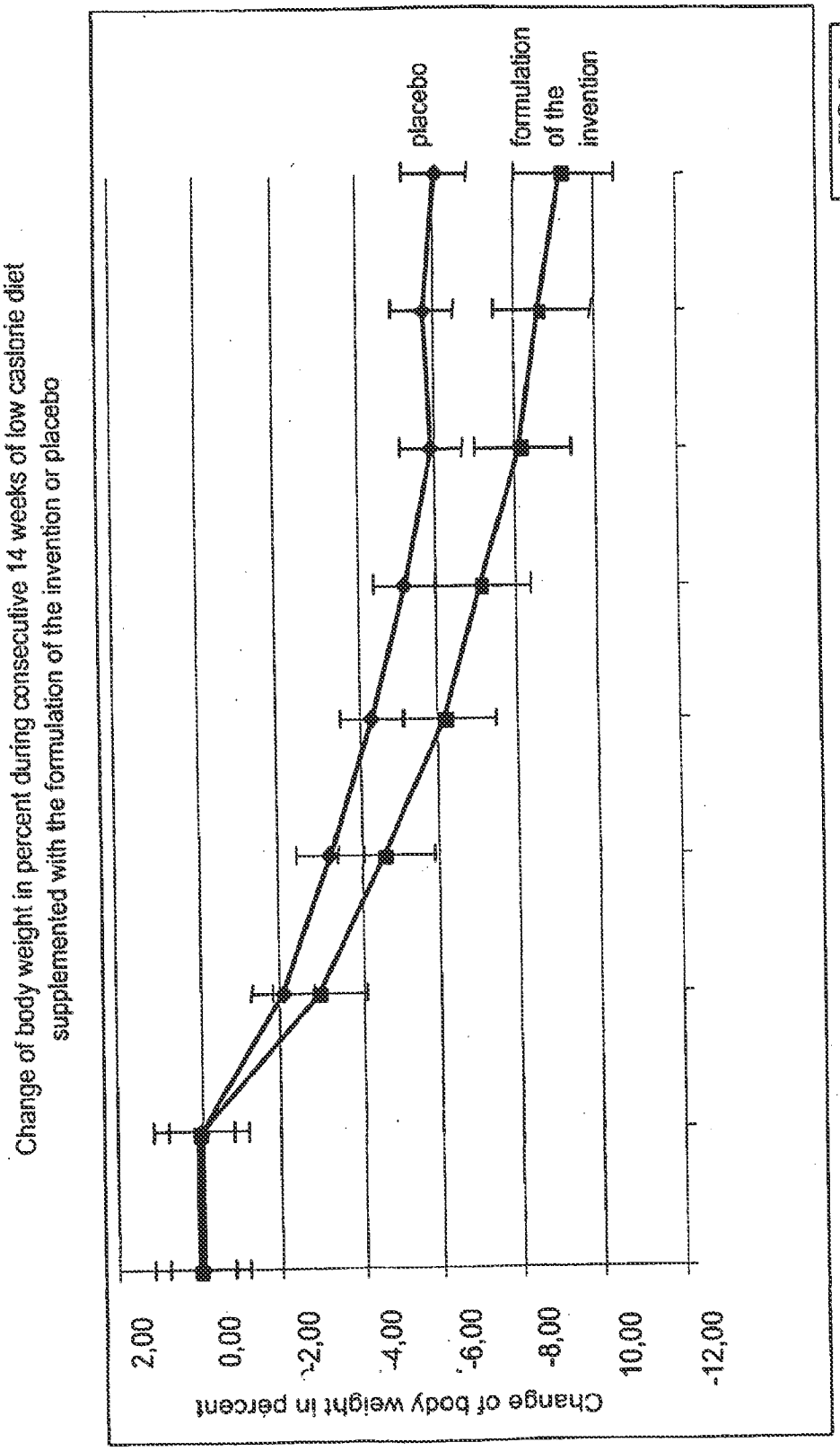
Change of body weight in percent during consecutive 14 weeks of low calorie diet supplemented with the formulation of the invention or placebo
Change of body weight in percent
2,00
0,00
-2,00
-4,00
-6,00
-8,00
10,00
-12,00
placebo
formulation of the invention

FIG.5

Exhibit 7

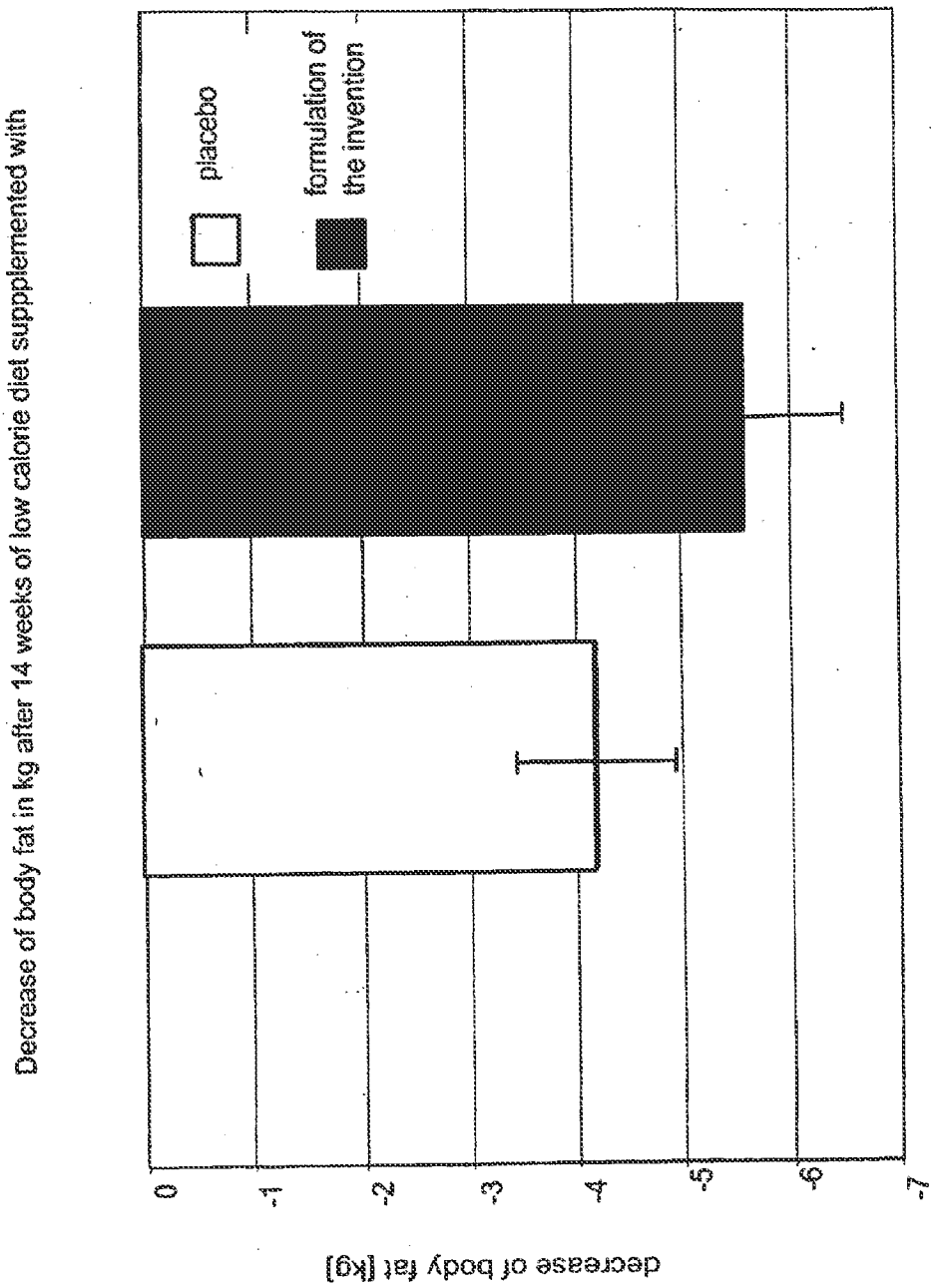
Decrease of body fat in kg after 14 weeks of low calorie diet suppplemented with
placebo
formulation of the invention
decrease of body fat [kg]
0
-1
-2
-3
-4
-5
-6
-7

FIG.6

Exhibit 8

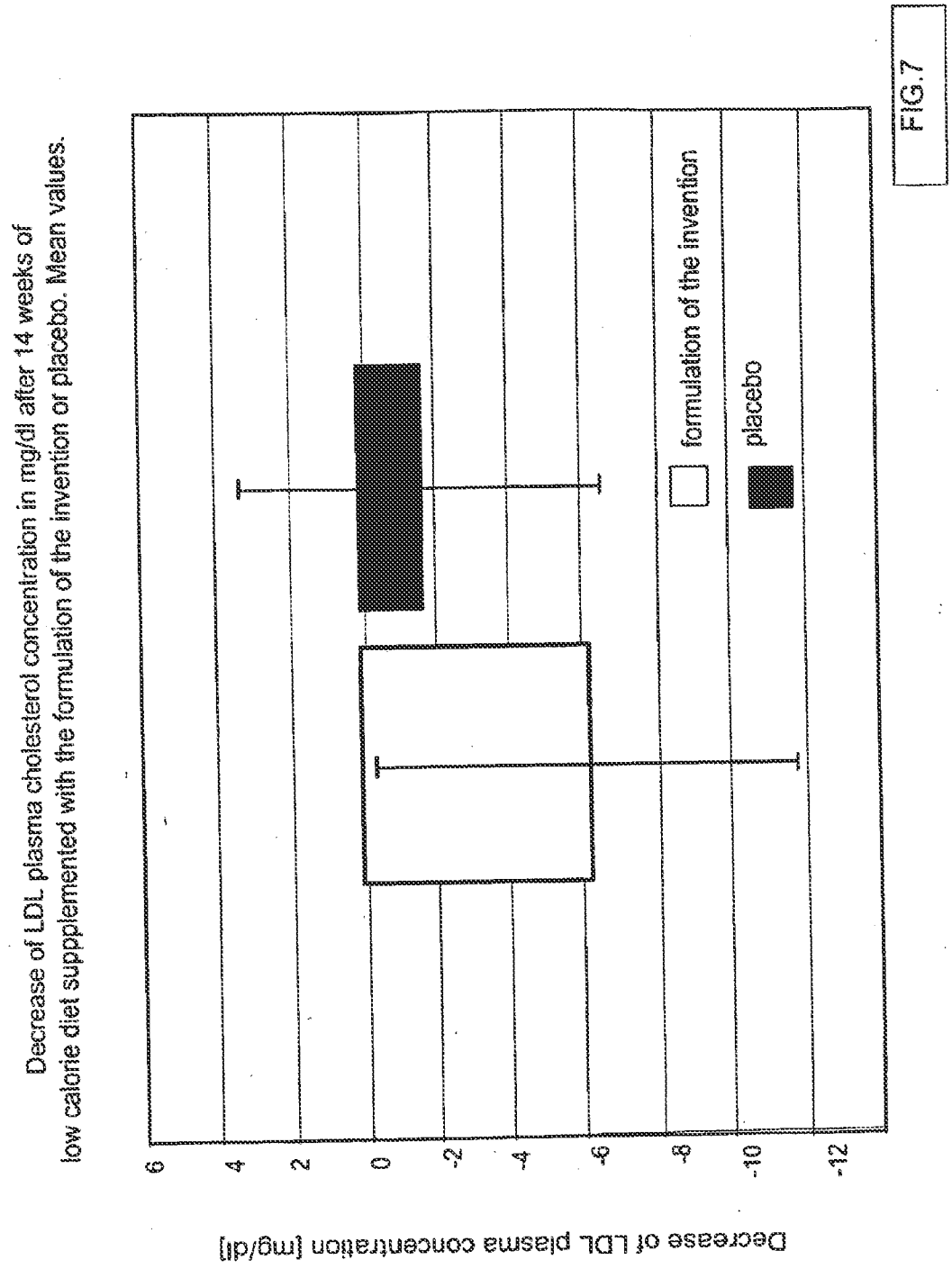
Decrease of LDL plasma cholesterol concentration in mg/dl after 14 weeks of low calorie diet suppplemented with the formulation of the invention or placebo. Mean values.
Decrease of LDL plasma concentration [mg/dl]
6
4
2
0
-2
-4
-6
-8
-10
-12
formulation of the invention
placebo

FIG.7

Exhibit 9

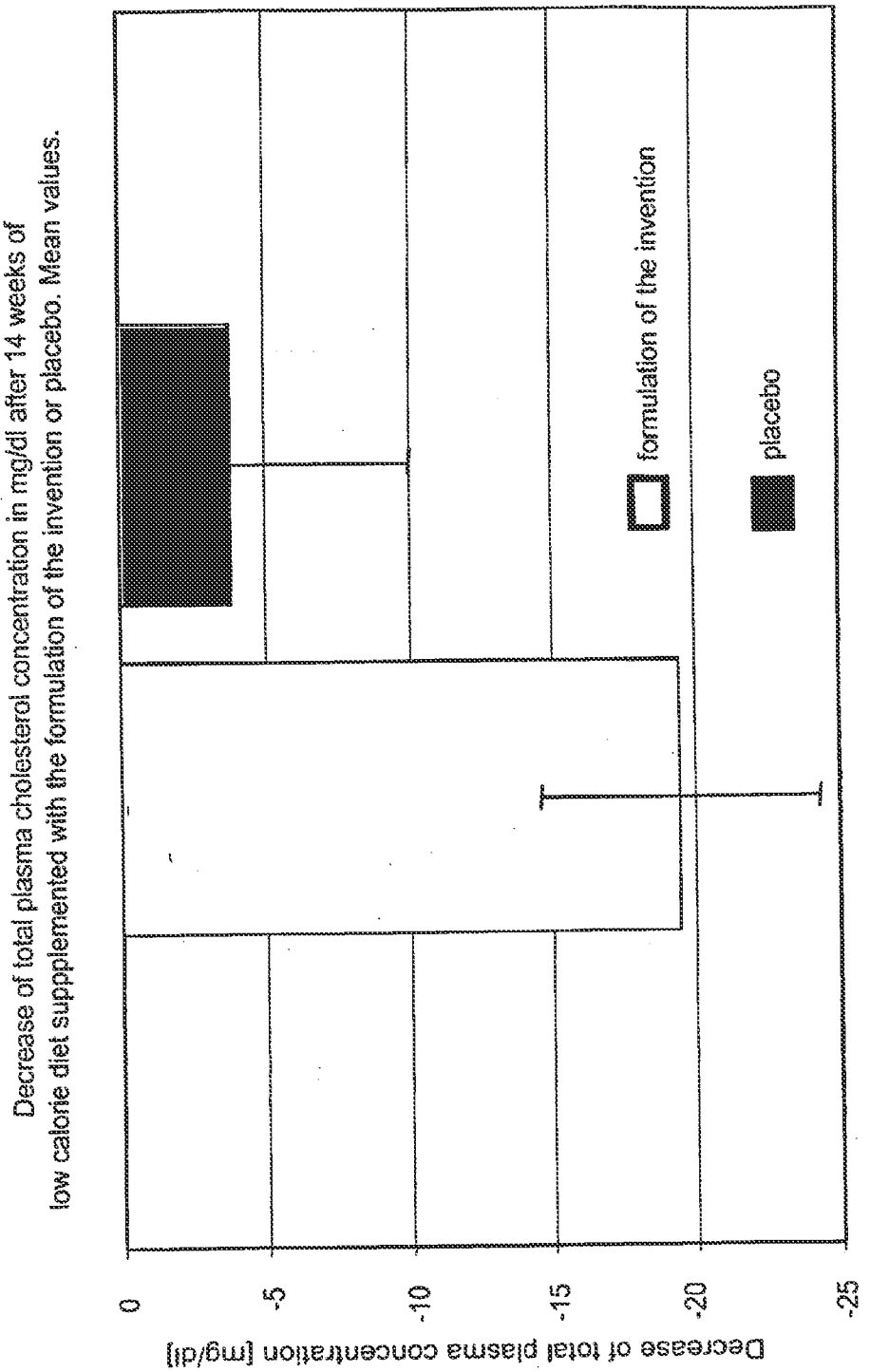
Decrease of total plasma cholesterol concentration in mg/dl after 14 weeks of low calorie diet supplemented with the formulation of the invention or placebo. Mean values.
Decrease of total plasma concentration [mg/dl]
0
-5
-10
-15
-20
-25
formulation of the invention
placebo

FIG.8

Exhibit 10

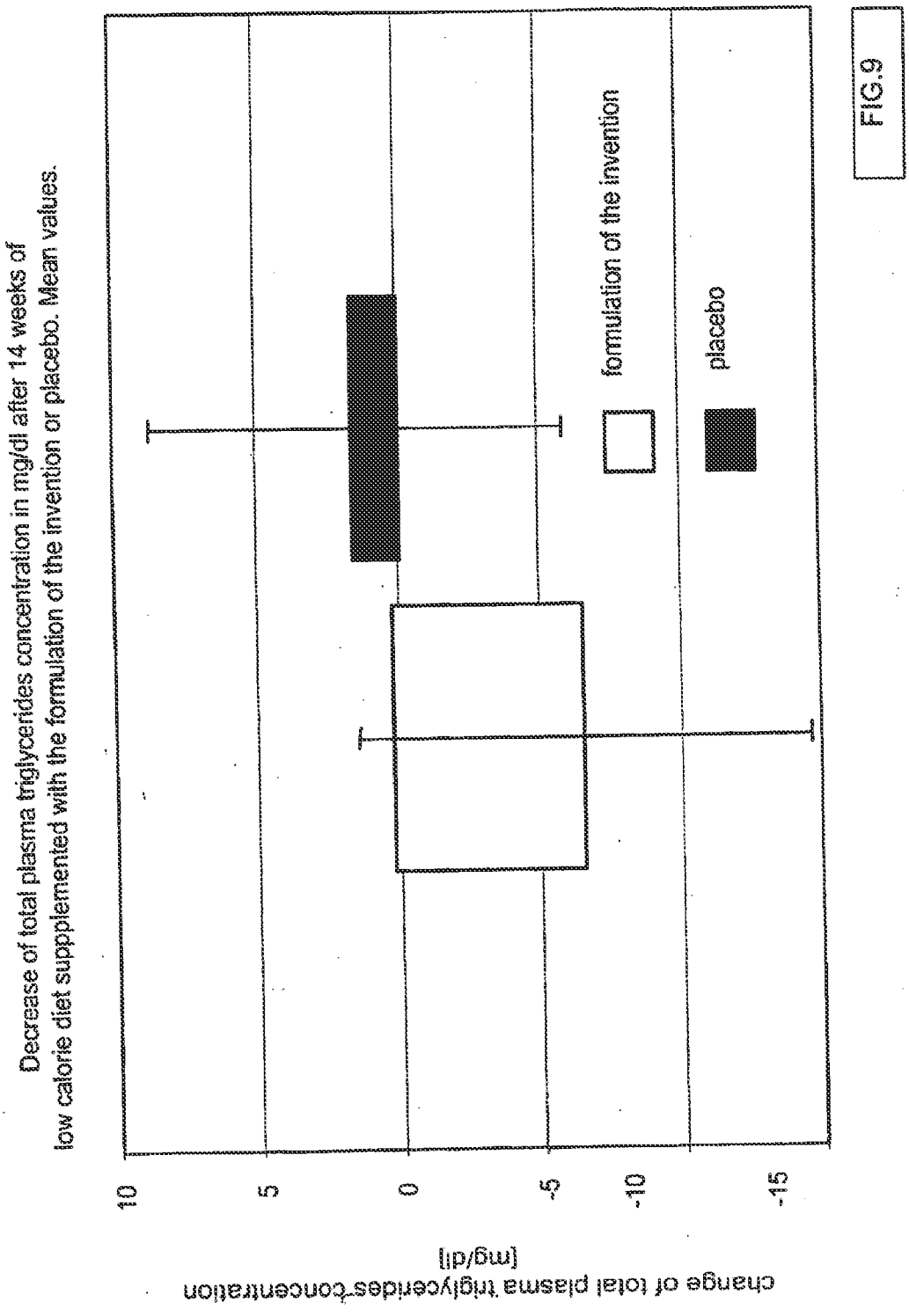
Decrease of total plasma triglycerides concentration in mg/dl after 14 weeks of
low calorie diet suppplemented with the formulation of the invention or placebo. Mean values.
change of total plasma triglycerides concentration
[mg/dl]
10
5
0
-5
-10
-15
formulation of the invention
placebo

FIG.9